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FOR IMMEDIATE RELEASE
July 13, 2006

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FCC BEGINS RULEMAKING TO ESTABLISH A NEW "MEDRADIO" SERVICE FOR MEDICAL RADIO COMMUNICATION DEVICES

Washington, D.C. – The FCC today initiated a proceeding to establish a new service for advanced medical radio communication ("MedRadio") devices in the 401-406 MHz band. The FCC noted that an ever-increasing number of medical devices are coming to rely upon radio transmissions for critical aspects of their functionality. These devices are improving the health care of all Americans by providing relief and recovery of function from many types of illness and injury.

In today's Notice of Proposed Rule Making, the FCC proposed designating an additional two-megahertz of spectrum for these devices, at 401-402 MHz and 405-406 MHz, adjacent to the existing Medical Implant Communications Service (MICS) band at 402-405 MHz, for a total of 5 megahertz specifically designated for medical device radiocommunications. Underscoring the flexibility and scope of potential uses under this new service, the FCC proposed to revise its nomenclature and designate the entire 401-406 MHz band as MedRadio service.

To accommodate a wider variety of devices than the current MICS service, which is limited to use of implant devices, the FCC proposed allowing the use of body-worn transmitting devices in the MedRadio service. The FCC also proposed increased flexibility for the newly designated 401-402 MHz and 405-406 MHz bands to allow the use of low power, low duty cycle MedRadio devices without requiring the frequency agility capability required by the current MICS rules. The FCC proposed that frequency agility would continue to be required of devices in the core 402-405 MHz band to accommodate devices that might be used for more critical purposes and which might be less compatible with non-frequency-agile devices, and sought comment on this point.

Additionally, in the Notice of Inquiry, the FCC sought comment on information concerning developments that are anticipated in the medical devices field and their likely spectrum requirements. Among other matters, the inquiry sought comment on:

- New implant and body-worn medical radiocommunication technologies and how the Commission could anticipate and proactively address the challenging array of RF spectrum issues.
- The relative benefits and tradeoffs that should be considered with respect to both licensed and unlicensed approaches to authorizing the operation of these devices.
- Collaborative efforts between this Commission (FCC) and the U.S. Food and Drug Administration (FDA) regarding options for better educating device manufacturing industry leaders about medical radio device electromagnetic immunity issues in an RF environment.

In the Order, the FCC granted an extension of a rule waiver to Biotronik, Inc. (the manufacturer of cardiac implant devices) for the continued operation of certain low power/short duration non-frequency-agile devices in 402-405 MHz MICS band, noting that it had earlier provided a similar condition for a waiver for DexCom, Inc. (the manufacturer of blood glucose monitoring implant devices). The FCC noted that the need for these waivers might be obviated by new rules when they are adopted; and that, if not, they would expire one year after new rules become effective.

Action by the Commission, July 13, 2006, by Notice of Proposed Rulemaking, Notice of Inquiry, and Order (FCC 06-103). Chairman Martin, Commissioners Copps, Adelstein, Tate, and McDowell. Separate statements issued by Chairman Martin, Commissioners Copps, Tate, and McDowell.

ET Docket Nos. 06-135, 05-213, 03-92, and RM-11271

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